

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF MISSOURI  
EASTERN DIVISION**

STATE OF MISSOURI,

*Plaintiff,*

v.

U.S. DEPARTMENT OF HEALTH AND  
HUMAN SERVICES, *et al.*,

*Defendants.*

Case No. 4:25-cv-00077-JAR

**MISSOURI'S MEMORANDUM IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS**

**TABLE OF CONTENTS**

<b>Table of Authorities .....</b>	<b>iii</b>
<b>Introduction.....</b>	<b>1</b>
<b>Factual Background.....</b>	<b>2</b>
I. HIPAA and the Final Rule .....	2
II. This Litigation.....	5
<b>Standard of Review.....</b>	<b>6</b>
<b>Argument .....</b>	<b>7</b>
<b>Conclusion .....</b>	<b>15</b>
<b>Certificate of Service &amp; Compliance.....</b>	<b>16</b>

## TABLE OF AUTHORITIES

### CASES

<i>Alfred L. Snapp &amp; Son, Inc. v. Puerto Rico ex rel. Barez</i> , 458 U.S. 592 (1982) .....	8, 10, 14
<i>Arkansas v. Dep’t of Educ.</i> , 742 F. Supp. 3d 919 (E.D. Mo. 2024) .....	11
<i>Biden v. Nebraska</i> , 600 U.S. 477 (2023) .....	12
<i>Dobbs v. Jackson Women’s Health Org.</i> , 597 U.S. 215 (2022) .....	3
<i>FDA v. All. for Hippocratic Med.</i> , 602 U.S. 367 (2024) .....	1
<i>Great Rivers Habitat Alliance v. FEMA</i> , 615 F.3d 985 (8th Cir. 2010) .....	6, 10, 11, 14
<i>Hekel v. Hunter Warfield, Inc.</i> , 118 F.4th 938 (8th Cir. 2024) .....	11, 13
<i>In re Admin. Subpoenas Duces Tecum Served Upon Missouri Baptist Med. Ctr. &amp; Missouri Baptist Hosp.-Sullivan</i> , 2022 WL 1802809, at *7 (E.D. Mo. June 2, 2022) .....	2
<i>Interstate Nat. Gas Association of America v. FERC</i> , 285 F.3d 18 (D.C. Cir. 2002) .....	13
<i>Iowa League of Cities v. EPA</i> , 711 F.3d 844 (8th Cir. 2013) .....	7, 13
<i>Lujan v. Defenders of Wildlife</i> , 504 U.S. 555 (1992) .....	1
<i>Lujan v. Nat’l Wildlife Fed’n</i> , 497 U.S. 871 (1990) .....	1
<i>Maine v. Taylor</i> , 477 U.S. 131 (1986) .....	8
<i>Missouri v. Biden</i> , 52 F.4th 362 (8th Cir. 2022) .....	7, 14
<i>Missouri v. Biden</i> , 738 F. Supp. 3d 1113 (E.D. Mo. 2024) .....	7
<i>Missouri v. Yellen</i> , 39 F.4th 1063 (8th Cir. 2022) .....	7
<i>Murthy v. Missouri</i> , 603 U.S. 43 (2024) .....	11
<i>Ohio v. Yellen</i> , 53 F.4th 983 (6th Cir. 2022) .....	13
<i>Purl v. HHS</i> , 2024 WL 5202497 (N.D. Tex. Dec. 22, 2024) .....	1, 4
<i>Rest. L. Ctr. v. U.S. Dep’t of Lab.</i> , 66 F.4th 593 (5th Cir. 2023) .....	12

<i>Tennessee v. EEOC</i> , 129 F.4th 452 (8th Cir. 2025).....	7–8, 12–14
<i>Texas v. United States</i> , 809 F.3d 134 (5th Cir. 2015).....	8
<i>Thunder Basin Coal Co. v. Reich</i> , 510 U.S. 200 (1994).....	13
<i>Whitney v. Guys, Inc.</i> , 700 F.3d 1118 (8th Cir. 2012) .....	12

## STATUTES

5 U.S.C. § 701.....	2
42 U.S.C. § 1320d-6 .....	2
42 U.S.C. § 1320d-7(b).....	2
Mo. Rev. Stat. § 191.910 .....	1, 5, 9, 10
Mo. Rev. Stat. § 407.040 .....	5, 10
Mo. Rev. Stats. § 334.100.7.....	10

## FEDERAL REGULATIONS

45 C.F.R. § 160.102.....	2
45 C.F.R. § 164.500 .....	2
45 C.F.R. § 164.502.....	3
45 C.F.R. § 164.509 .....	4
45 C.F.R. § 164.512.....	3, 9

## RULES

Fed. R. Civ. P. 9.....	1
------------------------	---

## **INTRODUCTION**

Defendants United States Department of Health and Human Services and Secretary Robert F. Kennedy, Jr., wisely make no attempt to defend their new HIPAA regulation on the merits. That regulation expressly contradicts the HIPAA statute and has already been preliminarily enjoined in another court. *See Purl v. HHS*, 2024 WL 5202497 (N.D. Tex. Dec. 22, 2024). Instead, Defendants raise only procedural objections, contending that the State of Missouri has not established standing. But in the next breath, they admit the complaint includes factual allegations of harm, including specific compliance burdens on Missouri. ECF 31, pp. 8–10. And they make no effort at all to address Missouri’s concern that the HIPAA regulation purports to invalidate Missouri law expressly requiring companies to turn over “*any* record relating to patient care” in response to a healthcare investigation. Mo. Rev. Stat. § 191.910.2 (emphasis added). Missouri easily has standing.

As to the compliance requirements the Final Rule imposes on Missouri, “Government regulations that require or forbid some action by the plaintiff almost invariably satisfy both the injury in fact and causation requirements.” *FDA v. All. for Hippocratic Med.*, 602 U.S. 367, 382 (2024). In such cases, standing is “easy” to establish. *Id.* (citing *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561–62 (1992)). Moreover, “[a]t the pleading stage, general factual allegations of injury resulting from the defendant’s conduct may suffice, for on a motion to dismiss [the Court must] presume that general allegations embrace those specific facts that are necessary to support the claim.” *Defenders of Wildlife*, 504 U.S. at 561 (quoting *Lujan v. Nat’l Wildlife Fed’n*, 497 U.S. 871, 889 (1990)) (cleaned up). Defendants’ motion ignores this standard and instead asks this Court to apply a heightened pleading requirement akin to the standard for alleging fraud, Fed. R. Civ. P. 9. The Court should decline.

The Final Rule injures Missouri on parallel fronts. *First*, Missouri is a directly regulated party and can thus challenge the regulation. *Second*, the regulation imposes sovereign harms by putting Missouri laws at preemption risk and impeding Missouri’s ability to conduct criminal and civil investigations. And *third*, as the Final Rule itself anticipated, Missouri is stuck footing the bill for various compliance costs, which are direct pocketbook injuries.

Because Missouri has established Article III standing to bring its claims under the Administrative Procedure Act, 5 U.S.C. § 701, *et seq.*, the motion to dismiss should be denied.

## **FACTUAL BACKGROUND**

### **I. HIPAA and the Final Rule**

The Health Insurance Portability and Accountability Act of 1996 generally protects certain “individually identifiable health information” from disclosure in some instances. 42 U.S.C. § 1320d-6. But this provision cannot be “construed to invalidate or limit the authority, power, or procedures established under any law providing for the reporting of disease or injury, child abuse, birth, or death, public health surveillance, or public health investigation or intervention.” *Id.* § 1320d-7(b).

In 2000, the Department adopted the “Privacy Rule,” 65 Fed. Reg. 82,462—which applies to certain “covered entities,” including “health care provider[s] who transmit[ ] . . . health information in electronic form.” 45 C.F.R. § 160.102; *see id.* § 164.500. While the Privacy Rule generally prohibits the disclosure of a patient’s protected health information (“PHI”) absent patient consent, it also “permits disclosure of PHI in specified circumstances, including but not limited to disclosures as required by law, disclosures for ‘health oversight,’ disclosure to law enforcement agencies, and disclosure for use in judicial proceedings.” *In re Admin. Subpoenas Duces Tecum Served Upon Missouri Baptist Med. Ctr. & Missouri Baptist Hosp.-Sullivan*, 2022 WL 1802809, at \*7 (E.D. Mo. June 2, 2022). The regulation expressly adopts a policy of permitting disclosure

in response to state law: “A covered entity may use or disclose protected health information to the extent that such use or disclosure is required by law and the use or disclosure complies with and is limited to the relevant requirements of such law.” 45 C.F.R. § 164.512(a).

On April 26, 2024, in response to *Dobbs v. Jackson Women’s Health Org.*, 597 U.S. 215 (2022), the Department promulgated the Final Rule, which limits the times when a covered entity may disclose protected health information in response to government requests for information related to “reproductive healthcare,” as defined by 45 C.F.R. § 164.502(a)(5)(iii). The Final Rule’s preamble specifies that “reproductive health care” should be “interpreted broadly and inclusive of all types of health care related to an individual’s reproductive system” and that it “encompasses the full range of health care related to an individual’s reproductive health.” 89 Fed. Reg. at 33,005. That definition includes medical interventions associated with “gender identity.” *See id.* at 33,006–07.

The Final Rule prohibits covered entities from disclosing PHI—even under 45 C.F.R. § 164.512—if those materials are sought:

- (1) [t]o conduct a criminal, civil, or administrative investigation into any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care[;]
- (2) [t]o impose criminal, civil, or administrative liability on any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care[; or]
- (3) [t]o identify any person [for these purposes].

45 C.F.R. § 164.502(a)(5)(iii)(A).

The Final Rule provides that “[a] covered entity or business associate may not use or disclose protected health information *potentially related* to reproductive health care . . . without obtaining an attestation that is valid under paragraph (b)(1) of this section from the person requesting the use or disclosure and complying with all applicable conditions of this part.” 45

C.F.R. § 164.509(a)(1) (emphasis added). Such attestation must contain a “description of the information requested” and “clear statement that the use or disclosures is not for a purpose” prohibited by the Final Rule. 45 C.F.R. § 164.509(c)(1).

The Final Rule also dictates that every attestation must include an acceptance by the signatory that they “may be subject to criminal penalties” if the attestation is later deemed defective. 45 C.F.R. § 164.509(c)(1)(v). An attestation is defective if the document has any of the following: (i) “lacks an element or statement required by [the Final Rule],” (ii) “contains an element or statement not required by [the Final Rule],” (iii) is “combined with any other document except where the other document is needed to satisfy the requirements” to be valid, (iv) the “covered entity or business association has actual knowledge that the attestation is false,” or (v) a “reasonable covered entity or business associate in the same position would not believe that the attestation is true.” 45 C.F.R. § 164.509(b)(2).

The Final Rule does not authorize law enforcement agencies to obtain information after submitting an attestation, but places the power to assess the validity of each attestation squarely within the discretion of the covered entity—even though the covered entity may have no legal expertise. 45 C.F.R. § 164.509(a)(1). While the Final Rule became effective on April 26, 2024, covered entities were generally not required to comply until December 23, 2024, but had until February 16, 2025, to amend their privacy notices. 89 Fed. Reg. at 32,976.

In December, a federal court preliminarily enjoined enforcement of the rule, concluding that it violates HIPAA’s plain text, which prohibits Defendants from passing any regulation that would “limit the authority, power, or procedures established under any law” for any “public health surveillance, or public health investigation or intervention.” *Purl*, 2024 WL 5202497 at \*7 (quoting § 1320d-7(b)) (emphasis deleted).



## II. This Litigation

On January 17, 2025, Missouri filed this action alleging that the Final Rule exceeds the Department’s authority and is arbitrary and capricious. ECF 1, ¶¶ 90–115. The Complaint alleges that the Final Rule is injuring “Missouri’s ability to root out fraud and abuse,” because it inhibits the Missouri Attorney General’s ability to investigate health care fraud, abuse, deception, and unfair practices under Mo. Rev. Stat. §§ 191.910, 407.040. *Id.* ¶¶ 1, 76–77. The Final Rule also frustrates investigations by Missouri executive agencies who “investigate abuse, neglect and financial exploitation of adults in nursing homes and other facilities, as well as some cases of Medicaid recipients who are abuse, neglected or financial exploited in their own homes” and “rely on medical records obtained from HIPAA-covered entities pursuant to civil investigatory demands.” *Id.* ¶ 78. In particular, the complaint noted that the regulation threatens to impede Missouri law, under which “health care providers are *required*” to produce “*any record* relating to patient care” in response to a healthcare investigation. *Id.* ¶ 77 (quoting Mo. Rev. Stat. § 191.910.2) (emphasis original).

The Complaint also alleges other various direct forms of sovereign, regulatory, and pocketbook injuries to Missouri, including:

- (1) “The Final Rule’s regime thus both imposes an unmanageable compliance burden on state officials and seeks to preempt state laws that conflict with HHS’s favored policies,” *id.* ¶ 57;
- (2) “The Final Rule’s barriers against disclosure also impede state officials and law enforcement agencies’ ability to obtain evidence of a crime, other potential violations of state law, or threats to public health related to ‘reproductive health care,’” *id.* ¶ 58;
- (3) “By requiring state agencies to instead come forward with specific factual information before obtaining records, the Final Rule sharply limits State investigative authority,” *id.* ¶ 60;

(4) “The processing of attestations with each demand produces administrative costs and requires investigators to spend time ensuring the attestation complies with the Final Rule,” *id.* ¶ 81;

(5) “[U]nder the Final Rule, state employees now must make attestations regarding issues that are unclear upon pain of criminal liability. The result is a chilling effect on the State’s ability to pursue typical investigations,” *id.*;

(6) “[T]he Missouri Department of Health and Senior Services (DHSS) and Missouri Department of Social Services (DSS) have begun to receive requests for attestations from health care providers in the State, regardless of the type of records sought” which “has significantly affected these agencies’ ability to conduct their day-to-day statutory responsibilities, and have been burdensome on their operations,” *id.* ¶ 82

(6) “Just recently, a covered-entity raised the Final Rule as a full bar to producing materials in response to a civil investigative demand from the Attorney General absent patient consent,” *id.* ¶ 83;

(7) “[T]he Final Rule requires both the investigators and the demand-recipient to determine that the demand complies with the Final Rule, and ultimately makes investigators’ receipt of information contingent on the demand-recipient’s determination that the attestation satisfies with the Final Rule,” *id.* ¶ 84;

(8) “The decision by Missouri health care providers to shield all medical records absent attestation” which is “hindering state investigations, and will continue to do so,” *id.* ¶ 85 (emphasis deleted); and

(9) The “Final Rule is currently necessitating a system-wide overhaul of state agencies’ processing systems for HIPAA requests,” which will cause “financial, logistical, and personnel burdens required to come into compliance with the Rule’s currently effective disclosure requirements for “reproductive health care” data are substantial,” *id.* ¶ 89.

On March 31, 2025, Defendants moved to dismiss for lack of subject matter jurisdiction and. ECF 31.

### **STANDARD OF REVIEW**

Where, as here, defendants press a “facial attack” against the complaint, the Court must “accept all factual allegations in the pleadings as true and view them in the light most favorable to the nonmoving party.” *Great Rivers Habitat Alliance v. FEMA*, 615 F.3d 985, 988 (8th Cir. 2010). “Plaintiffs bear the burden of proving that subject matter jurisdiction exists.” *Missouri v. Biden*,

738 F. Supp. 3d 1113, 1139 (E.D. Mo. 2024) (citation omitted). “At the pleading stage, general factual allegations of injury resulting from the defendant’s conduct may suffice, for on a motion to dismiss [the Court must] presume that general allegations embrace those specific facts that are necessary to support the claim.” *Defenders of Wildlife*, 504 U.S. at 561 (cleaned up). The Court has substantial discretion and is “free to weigh the evidence and satisfy itself as to the existence of its power to hear the case.” *Missouri v. Biden*, 738 F. Supp. 3d at 1139 (citation omitted).

### **ARGUMENT**

Missouri’s Complaint contains more than enough to establish Article III standing at the pleading stage. *Defenders of Wildlife*, 504 U.S. at 561. “To avoid dismissal for lack of standing, [a plaintiff] must allege sufficient facts to support a *reasonable inference* that they can satisfy the elements of standing.” *Missouri v. Biden*, 52 F.4th 362, 368 (8th Cir. 2022) (quoting *Missouri v. Yellen*, 39 F.4th 1063, 1068 (8th Cir. 2022) (quotation marks omitted) (emphasis added)). Defendants argue only that Missouri has not pleaded an “injury in fact.” Defendants are wrong. Missouri has pleaded many.

1. Start first with the State’s status as a directly regulated party. Defendants do not dispute that the rule regulates Missouri and its agencies. That is sufficient to reject Defendants’ motion. When a plaintiff is the object of a regulatory action, “there is ordinarily little question that the action or inaction has caused the plaintiff injury, and that a judgment preventing or requiring the action will redress it.” *Tennessee v. EEOC*, 129 F.4th 452, 457 (8th Cir. 2025) (quoting *Defenders of Wildlife*, 504 U.S. at 561–62) (alteration adopted). That is because a regulated party has “a concrete interest in avoiding regulatory obligations above and beyond those that can be statutorily imposed upon them.” *Id.* (quoting *Iowa League of Cities v. EPA*, 711 F.3d 844, 871 (8th Cir. 2013)) (alteration adopted). In *Tennessee v. EEOC*, seventeen states brought an APA suit challenging a final rule promulgated by the EEOC, that required States as employers to make

certain accommodations to employees. *Id.* at 456. The district court held that the States lacked standing, but the Eighth Circuit reversed because “the States in this case are the direct objects of the EEOC’s rule.” *Id.* at 457–48. So too here. As health-plan administrators and healthcare providers, Missouri’s HIPAA-covered entities must disclose (or withhold) HIPAA-protected information consistent with the Final Rule. That is enough to establish standing. *Id.* at 458 (stating an entity that is “the object of” a new regulation need not also establish “specific economic harms” or “a credible threat of enforcement if they refused to comply.” (citation omitted)).

Defendants deny none of this. Instead they insist (at 10) that the complaint has not identifies “which state agencies” are affected. That is neither true nor required to be included in a complaint. It is not required because, “[a]t the pleading stage, *general* factual allegations of injury” are sufficient, as courts must “presume that general allegations embrace those specific facts that are necessary to support the claim.” *Defenders of Wildlife*, 504 U.S. at 561 (cleaned up) (emphasis added). Missouri is not required at the complaint stage to identify with particularity which agencies are affected. But in any event, Missouri did provide examples, stating that the “Department of Health and Senior Services” and “Department of Social Services” have been “significantly affected,” and “their day-to-day statutory responsibilities” are being impeded. ECF 1 ¶ 82.

2. Then there is the core sovereign harm. Missouri has a “sovereign interest[ ]” in “the power to create and enforce a legal code.” *Alfred L. Snapp & Son, Inc. v. Puerto Rico ex rel. Barez*, 458 U.S. 592, 601 (1982). “[F]ederal preemption of state law” and “federal interference with the enforcement of state law” both create standing. *Texas v. United States*, 809 F.3d 134, 153 (5th Cir. 2015), *aff’d by an equally divided court*, 579 U.S. 547 (2016). That is because “a State clearly

has a legitimate interest in the continued enforceability of its own statutes.” *Maine v. Taylor*, 477 U.S. 131, 137 (1986).

The rule threatens to disrupt that interest. In particular, Defendants entirely ignore the part of the complaint that discusses the requirement in Missouri law that healthcare providers turn over “any record” in response to the State launching a healthcare investigation. ECF 1 ¶ 77; Mo. Rev. Stat. § 191.910. That provision is plainly consistent with HIPAA *before* the new rule because HIPAA’s other regulations expressly say that “[a] covered entity may use or disclose protected health information to the extent that such use or disclosure is required by law.” 45 C.F.R. § 164.512(a). But after the new rule, Missouri law faces preemption risk. Indeed, as Missouri also alleged, litigants have begun citing the new HIPAA rule as a reason not to comply with the State’s healthcare investigations, and many of those investigations are now tied up in litigation. ECF 1 ¶ 83.

Similarly, Missouri has alleged sufficient facts to support a reasonable inference that the Final Rule injures the State’s sovereign interest in investigating criminal and civil violations of state law. Defendants argue (at 8) that “the complaint lacks . . . any well-pleaded ‘specific facts’ explaining how the Rule is *actually* impeding any investigations.” ECF 31 at 8 (citation omitted). This argument is perplexing. In the very next sentence, Defendants admit that the Complaint alleges covered entities have demanded attestations from Missouri’s investigative agencies under the Final Rule and that it has “significantly affected these agencies’ ability to conduct their day-to-day statutory responsibilities.” ECF ¶ 82. Despite this admission, Defendants suggest the Complaint cannot establish standing because it does not identify “what records these agencies have requested and for what purposes” or “whether the Rule actually required an attestation in any particular instance,” among other inconsequential queries. ECF 31 at 8. At the pleading stage, no

such exactitude is required. Instead, “general factual allegations of injury resulting from the defendant’s conduct may suffice,” because the Court must “presume that general allegations embrace those specific facts that are necessary to support the claim.” *Defenders of Wildlife*, 504 U.S. at 561 (cleaned up).

In any event, that is not the only allegation of harm in the Complaint. Defendants also admit (at 9 n.1) that the Complaint alleges that a covered entity has raised the Final Rule “as a full bar to producing materials in response to a civil investigative demand.” ECF 1 ¶ 83. The Complaint further alleges that the Final Rule “impede[s] state officials and law enforcement agencies’ ability to obtain evidence of a crime, other potential violations of state law, or threats to public health related to ‘reproductive health care,’” *id.* ¶ 60, “sharply limits State investigative authority” “[b]y requiring state agencies to [ ] come forward with specific factual information before obtaining records,” *id.* ¶ 60, and creates “a chilling effect on the State’s ability to pursue typical investigations” by forcing “state employees [to] make attestations regarding issues that are unclear upon pain of criminal liability,” *id.* ¶ 81. The Court must accept these factual allegations “as true and view them in the light most favorable to [Missouri].” *Great Rivers*, 615 F.3d at 988.

Each of these allegations implicates Missouri’s interest in “the exercise of sovereign power over individuals and entities within the relevant jurisdiction.” *Snapp*, 458 U.S. at 601. Missouri statutes grant investigative authority to the Missouri Attorney General, Missouri executive agencies, and the Missouri Board of Registration for the Healing Arts to investigate actual—and potential—violations of Missouri law. *See, e.g.*, §§ 191.910, 407.040, 334.100.7. Those statutes *require* that covered entities disclose PHI. *Id.* The Final Rule, however, creates a barrier to such disclosure. Thus Final Rule “seeks to regulate [HIPAA] in a manner that is [arguably] not

compatible with [those] laws.” *Arkansas v. Dep’t of Educ.*, 742 F. Supp. 3d 919, 928 (E.D. Mo. 2024). That injury establishes Article III standing. *Id.*

Defendants remaining arguments do not affect this calculus. For starters, Defendants’ reliance on *Murthy v. Missouri* is misplaced. 603 U.S. 43 (2024). In *Murthy*, the case came before the Supreme Court on a preliminary injunction motion where “the parties ha[d] taken discovery.” *Id.* at 58. At that stage, the Court noted that “plaintiff must make a ‘clear showing’ that she is ‘likely’ to establish each element of standing” with “factual evidence,” and “cannot rest on ‘mere allegations’” as would have been sufficient at the motion to dismiss stage. *Id.* At the motion to dismiss stage, Missouri need not establish a “clear showing” with “factual evidence,” because the Court must accept the well-pleaded allegations as true, *Great Rivers*, 615 F.3d at 988, and “presume that general allegations embrace those specific facts that are necessary to support the claim,” *Defenders of Wildlife*, 504 U.S. at 561 (cleaned up).

No better is Defendants’ reference to *Hekel v. Hunter Warfield, Inc.*, 118 F.4th 938 (8th Cir. 2024). In *Hekel*, the plaintiff alleged injury in the form of a “violation of her federal ‘statutory rights,’” an “informational injury”; “predictions of a future ‘risk of tangible harm’”; and “‘confus[ion],’ ‘worry,’ and ‘sleeplessness.’” *Id.* at 941. The Eighth Circuit concluded that the plaintiff could not establish standing because she had not pleaded a cognizable harm. *Id.* at 942–44. Here, Missouri has pleaded a cognizable harm as the Final Rule “interferes with [its] sovereign right to create and enforce [its] laws.” *Arkansas*, 742 F. Supp. 3d at 928. That is sufficient for Article III standing.

3. Finally, there are pocketbook injuries. Defendants concede (at 9)—that Missouri has alleged “it must expend resources to comply with the Rule’s requirements.” That is enough. It is

well established that “financial harm is an injury in fact.” *Biden v. Nebraska*, 600 U.S. 477, 490 (2023).

Defendants nonetheless insist (at 10) that the State did not provide enough detail about these costs. But the State need only provide “general factual allegations of injury.” *Defenders of Wildlife*, 504 U.S. at 561. And in any event, the State did provide specifics. Indeed, the Final Rule itself details some of these costs.<sup>1</sup> See 89 Fed. Reg. at 33,049 (anticipating costs for covered entities, including: implementing the attestation requirement, responding to requests for the use or disclosure of PHI; revising policies and procedures; and revising training programs for employees). The Department estimated that covered entities would incur administrative costs amount to \$595 million in the first year alone, with ongoing costs in the tens of millions “related to the attestation requirement.” *Id.* By its own terms, the Final Rule identifies extra costs that Missouri HIPAA-covered entities will incur due to its mandates. That is enough to establish Article III standing. See *Rest. L. Ctr. v. U.S. Dep’t of Lab.*, 66 F.4th 593, 600 (5th Cir. 2023) (finding plaintiff need not “convert each allegation of harm into a specific dollar amount,” because it is sufficient to plead that the State “will incur exactly the kinds of continuing compliance costs predicted by the Department itself.”)

*Tennessee v. EEOC* is again instructive. There, as here, a Government defendant argued that plaintiff states lacked standing because they did “not try to quantify, or clearly explain, the costs associated” with the challenged rule. Appellee Br. at 24, No. 24-2249 (6th Cir. Aug. 23, 2024) (quotation marks omitted). The Government defendant also argued that costs “would only

---

<sup>1</sup> The Final Rule was included, and incorporated, in the Complaint as Exhibit A, ECF 1-1, and is properly considered as part of the pleading. *Whitney v. Guys, Inc.*, 700 F.3d 1118, 1128 (8th Cir. 2012).



be incurred if such an accommodation is requested,” and any compliance before such an event was taken “voluntarily.” *Id.* at 25. The Eighth Circuit firmly rejected these arguments, holding:

The agency’s notion of actions undertaken “voluntarily” is inconsistent with the realities facing these regulated parties. Covered entities must comply with the Rule, and we presume that the States will follow the law as long as the Rule is in effect. An employer cannot meet its obligations under the Rule without taking steps to ensure that its employees know their rights and obligations under the Rule. As a practical matter, the Rule requires immediate action by the States to conform to the Rule, and this action produces an injury in fact.

129 F.4th at 458 (citing *Iowa League of Cities*, 711 F.3d at 870); *see also Thunder Basin Coal Co. v. Reich*, 510 U.S. 200, 220- 21 (1994) (Scalia, J., concurring in part) (“complying with a regulation later held invalid almost always produces the irreparable harm of nonrecoverable compliance costs.”). Where HIPAA-covered entities “cannot meet [their] obligations under the Rule without taking steps to ensure that [their] employees know their . . . obligations under the Rule” and “the Rule requires immediate action by the States to conform to the Rule,” those actions produce an injury in fact in terms of compliance costs. *Tennessee v. EEOC*, 129 F.4th at 458.

The cases relied on by Defendants (at 10) are easily distinguishable. In *Hekel*, the plaintiff alleged “out-of-pocket costs” and lost “time and money,” but did not link those allegations to the defendants’ actions. 118 F.4th at 943. In *Ohio v. Yellen*, the Sixth Circuit rejected two compliance costs arguments because one was not traceable to the challenged regulation and the second was never alleged in the complaint. 53 F.4th 983, 994 (6th Cir. 2022). And in *Interstate Nat. Gas Association of America v. FERC*, the D.C. Circuit reasonably rejected plaintiff’s assertion of incurring “significant expense,” which was raised only in a reply brief, while also acknowledging that “compliance costs often constitute an injury-in-fact.” 285 F.3d 18, 46 (D.C. Cir. 2002). Here, the Complaint alleges that Missouri’s HIPAA-covered entities are bearing costs related to compliance with the Final Rule’s mandates, consistent with the costs identified in the Final Rule itself. *See*, ECF 1 ¶¶ 57 (“The Final Rule’s regime . . . imposes an unmanageable compliance

burden on state officials); *id.* ¶ 81 (“The processing of attestations with each demand produces administrative costs”); *id.* ¶ 89 (“[The] Final Rule is currently necessitating a system-wide overhaul of state agencies’ processing systems for HIPAA requests” and causing “substantial” “financial, logistical, and personnel burdens”); *see also* 89 Fed. Reg. at 33,049.

Defendants remaining argument is equally off mark. Defendants’ suggestion (at 10) that the Court view Missouri’s allegations with “skepticism” ignores the relevant pleading standards and improperly attempts to heighten Missouri’s burden. *Great Rivers*, 615 F.3d at 988 (finding the Court must “accept all factual allegations in the pleadings as true and view them in the light most favorable to the nonmoving party”); *Defenders of Wildlife*, 504 U.S. at 561 (finding the Court must “presume that general allegations embrace those specific facts that are necessary to support the claim” (cleaned up)).<sup>2</sup>

\* \* \*

In short, Missouri’s Complaint “allege[s] sufficient facts to support a reasonable inference that [it] can satisfy the elements of standing.” *Missouri v. Biden*, 52 F.4th at 368. Those facts include allegations that the Final Rule impairs Missouri’s sovereign interest in “the exercise of sovereign power over individuals and entities within the relevant jurisdiction” by hindering its investigations into criminal and civil violations of state law, *Snapp*, 458 U.S. at 601, as the direct object of regulatory action faced with immediate compliance with the Final Rule, *Tennessee v. EEOC*, 129 F.4th at 457–48, and as an entity suffering pocketbook harm.

---

<sup>2</sup> Defendants cast aspersions against Missouri for having some paragraphs that are similar to Tennessee’s complaint challenging the same rule, which was filed the same day as Missouri’s complaint. But it is hardly unusual for two different plaintiffs, both contemplating bringing similar legal actions to collaborate with each other and sometimes share work product.

**CONCLUSION**

For these reasons state above, Missouri requests that this Court deny Defendants’ motion to dismiss under Rule 12(b)(1).

Dated: April 14, 2024

Respectfully submitted,

**ANDREW BAILEY**  
ATTORNEY GENERAL

/s/Joshua M. Divine  
Joshua M. Divine, #69875(MO)  
*Solicitor General*  
Reed C. Dempsey, #1697941(DC)  
*Deputy Solicitor General*  
OFFICE OF THE ATTORNEY GENERAL  
207 W. High Street  
Jefferson City, MO 65101  
Tel: (573) 751-0812  
Fax: (573) 751-0774  
Joshua.Divine@ago.mo.gov  
Reed.Dempsey@ago.mo.gov

*Counsel for Plaintiff State of Missouri*

**CERTIFICATE OF SERVICE & COMPLIANCE**

I certify that on April 14, 2025, a true and accurate copy of the foregoing document was electronically filed through the Court's CM/ECF System and that a copy of the foregoing will be sent via email to all parties by operation of the Court's electronic filing system, consistent with Federal Rule of Civil Procedure 5(b).

I further certify that the foregoing document contains 4,523 words in 15 pages, exclusive of matters designated for omission, as counted by Microsoft Word, and complies with Local Rule 4.01(D).

/s/ Joshua M. Divine

*Counsel for Plaintiff State of Missouri*